

VIA FACSIMILE (703) 872-9306

**IN THE DRAWINGS**

Replacement Sheets are submitted herewith for Figures 1, 2, 6, 7 and 8. Please replace original sheets having Figures 1-2, 6-8 with the Replacement Sheets submitted herewith.

The following changes were made to the Figures:

Fig. 1. Numbers "150" added with lead lines from the number to the touch memory device/data buttons located on the supply and waste cartridge 15, 10, respectively.

Fig. 2. Wire connections added to show electrical communication to and from battery 85, keypad 75, microcontroller, drive motor 50/250, data buttons 150, safety interlock sensor 155; element "100" number deleted and replaced with "95"; added data buttons 150 on cartridges 10, 15.

Fig. 6. Box containing words "Safety Interlocks" added, including arrow to and from Microcontroller.

Fig. 7. Numbers "150" added with lead lines from the number to the touch memory device/data buttons located on the supply and waste cartridge 15, 10, respectively.

Fig. 8. Numbers 150 added with lead lines from the number to the touch memory device/data buttons located on the supply and waste cartridge 15, 10, respectively. Touch memory device/data buttons added to the supply and waste cartridges 15, 10, respectively. Wire connections added to show electrical communication to and from battery 85, keypad 75, microcontroller, drive motor 50/250, data buttons 150, safety interlock sensor 155. Added number 22 and lead line. Added safety interlock sensor 155 to area under supply cartridge 215.

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**Remarks**

Claims 1-13 were previously withdrawn for being directed to unelected claims, and are canceled herein. Claims 14 and 15 were previously finally rejected and have been amended herein to meet the Examiner's observations regarding means-plus-function language. No new matter has been added thereby. The Examiner's drawing objections and claim rejections are discussed below. For the reasons given below Applicants respectfully request reconsideration of the application, and passage to allowance.

**1. Election/Restriction.**

Applicants agree that claims 1-13 are withdrawn as being directed to a non-elected species. Furthermore claims 1-13 are now cancelled herein without prejudice to their being reintroduced in a subsequent divisional application.

Since there appears to be no dispute over these facts, Applicants respectfully request the Examiner to withdraw whatever objection he may have, and reconsider the application, or specifically point out what continuing basis for objection remains.

For the foregoing reasons, Applicants respectfully request the Examiner to withdraw the objection, and reconsider the application.

**2. Objections to Drawings**

The Examiner has objected to the drawings on the basis that the term "electrical communication" must be shown in the drawings or cancelled from the claims. Figures 6 and 8 have been amended to show one means of electrical communication (wiring) and are included in this submission. Applicants reassert that the term "electrical communication" is a well-used term of art that simply points out that the components are electrically connected and able to exchange information and/or power electronically. It is well within the ordinary skill of the art to understand that "electrical communication" requires wires, or infrared signaling apparatus, or microwave communication, or wireless communication, or printed circuit boards, or any other

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known mode of electrical communication to allow control and communication between and amongst the various components shown in the Figures. This concept is ably elucidated by the Federal Circuit in the *Christianson v. Colt Industries* case wherein it said that "Patents are not production documents . . . [T]he law requires that patents disclose inventions, not mass-production data, and that patents enable the practice of inventions, not the organization and operation of factories." *Christianson v. Colt Industries*, 822 F. 2d 1544, 1562 (Fed. Cir. 1987).

Figure 6 is a schematic of the electronic control circuit showing the lines representing electrical communication. With respect to the figure, the microcontroller (center of the figure) is connected to the left by arrows to the Display, Keypad, Supply and Waste Cartridge Data Buttons, an arrow up from below to the battery, and to the right by an arrow to the drive motor and safety interlocks. Safety interlocks originally shown in Figures 2 and 8 have been added to the schematic of Figure 6. The arrows are commonly understood in the art to represent lines of communication or power transmission, with two-headed arrows indicating bidirectional flow. This can be interpreted as, in the case of the Display, that it receives data from the microcontroller to drive the display LEDs, a well-known function of microcontrollers. In the case of the battery, power flows from the battery to the controller in the direction of the arrow. Therefore, the term "electrical communication" is amply illustrated in the drawings.

For the foregoing reasons, Applicants respectfully request the Examiner to withdraw the objection, and reconsider the application.

3. Rejection of claims 14-15 under 35 USC § 112, Second Paragraph

The Examiner has repeated his previous § 112, Second Paragraph rejection of claims 14 and 15 for being indefinite because it "is not clear what 'electronic control means for integrating all of the functions of the apparatus' encompass." The Examiner further states that they are indefinite because there is no explanation how the electronic control means integrates all of the functions, and all of the functions are not disclosed in the claims. Applicants have addressed this rejection in their Reply filed January 14, 2005, however it was not acknowledged in this Official Action by the Examiner. Applicants therefore repeat their arguments here by incorporating their previous arguments by reference. However, to summarize them, Applicants previously quoted directly from the detailed description the components included in the "electronic control means" as the components depicted schematically in Fig. 6 including the microcontroller 70, display 80,

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keypad 75 containing fingerpad switches 76, 77, battery 86, drive motor 50 or 250, waste and supply cartridge touch memory data buttons 150 and readers (not shown but incorporated by reference). Other electronic control means include electronically-controlled cartridge locks, safety interlock switches 155, and means for electrical communication. The functions include 1) the electronic control means that control the coordination of the blade changing process, and 2) the safety interlock function. Both are detailed throughout the detailed description, but attention is drawn to the following portions: p. 5 lines 6-7; p. 6 lines 13-17; p. 10 lines 15 – p. 11 line 12; p. 11 line 13- p. 14 line 14.

For the foregoing reasons, Applicants respectfully request the Examiner to withdraw the objection, and reconsider the application.

4. Rejection of claims 14-15 under 35 USC 103 over Pickett '600 in view of Schaller '858 and Tamura (US 6651538 B2)

The Examiner has rejected claims 14 and 15 as being unpatentable under 35 USC 103 over Pickett '600 in light of Schaller '858 and Tamura '538. Applicants respectfully traverse this basis of rejection for the following reasons.

Applicants responded to the rejection of claims 14-15 for obviousness over Pickett '600 in view of Schaller '858 on January 14, 2005. The principle difference here is that the Examiner has added Tamura '538 for teaching an electric motor and motor pulley, admittedly missing from the Pickett-Schaller combination. Applicants observe that Tamura is not prior art in that its filing date of Nov. 25, 2002 (and hence 102(e) date) is later than Applicants' priority date (April 27, 2001) by more than a year, and hence cannot be cited against the application.

Applicants therefore repeat and incorporate by reference their previous argument that no *prima facie* case of obviousness has been established by the Examiner. The Examiner has provided no incentive to combine the teachings of Pickett, which describes a manual micotome device having standard user-replaced blades, and the centerless grinder of Schaller, which verges on being nonanalogous art. In any event, none of the art cited discloses, describes or even suggests the automation of the blade changing procedure and the electronic controls that effectuate that, not to mention the safety interlock features also described and claimed.

For the foregoing reasons, Applicants respectfully request the Examiner to withdraw the rejection of claims 14 and 15 for obviousness, and reconsider the application.

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**5. Response to Arguments**

The Examiner included a paragraph entitled "Response to Arguments" which addresses two issues regarding the election of species, and the "electrical communication" language. Regarding the election of species, Applicants cannot discern either a question or a request from the Examiner. The application is presently being examined as to claims 14 and 15, and in an effort to advance prosecution, Applicants believe that there is presently no issue regarding the patentability of the claims being addressed by this discourse. Therefore, Applicants are not responding to the Examiner's comments at this time.

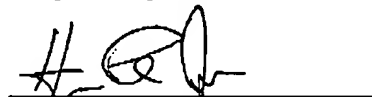
Regarding the second issue raised, Applicants position is that original Figure 6 shows the electrical communication feature. However, in an effort to advance prosecution, Applicants have amended the drawings to more particularly show and distinctly point out the electrical communication feature. In Fig. 1 only pre-existing numbers were added; in Fig. 2 traces showing the wiring outlined in Fig. 6 were added, and the blade number was corrected from 100 to 95; in Fig. 6 the safety interlocks 155 discussed in the specification on page 10 line 15 through page 11 line 12 and shown in Figs. 2 and 8 were added; in Fig. 7 the numbers 150 were added to indicate the data buttons; in Fig. 8 the data buttons and their numbers 150 were added, wire connections were added to show electrical communication between the various electronic control elements, the safety interlock sensor shown in original Figure 2 was added, and number 22 with a lead line was added. No new matter was added by any of these additions.

Finally, the Examiner has pointed out that it was not apparent to him that element 60 (driveshaft pulley) could operate in conjunction with motor gear 55. Applicants have amended the specification to change the driveshaft pulley to a gear.

Applicants respectfully submit that all of the Examiner's basis of objection and rejection have been met or overcome by these arguments and amendments, and reconsideration of the application is therefore respectfully requested.

Date: 7/20/05

Respectfully submitted,



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### Related Applications

This application is a continuation-in-part of commonly assigned U.S. Serial Number 09/562,270, filed April 29, 2000.

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### Background

#### 1. Field of the Invention

The present invention is directed to apparatus for use in preparing tissue sections for use in diagnostic histopathology and, more particularly, to an apparatus that automatically changes the blades of a microtome without exposure of the user to the cutting edges of the blades.

#### 2. Description of Related Art

Microtomes have been used for many years to meet the exacting requirements necessary for thin sectioning of paraffin-embedded tissue. Essentially, microtomes are holders for razor-sharp metal blades, against which a block of paraffin-embedded tissue is moved in an up-and-down motion. Concurrently, either the tissue block is advanced against the blade, or vice versa, so that with each up or down stroke, a thin slice or "section" of tissue is cut from the block. The blades are highly engineered for the precise requirements of tissue sectioning. Specifically, the blades are capable of cutting sections as thin as 1  $\mu$ m.

The present practice for tissue sectioning requires the blades be changed as they become dulled. This necessitates alleviating the pressure that the blade holder puts on the blade to keep it in place, usually by removing a clamping mechanism. Once the clamp is removed, the blade can be lifted off of the rest. Usually, this is accomplished by grasping the blade at an edge and discarding it in a sharps container, all of which is done by hand. This exposed the user to the edges of the blade, and of course the potential of serious injury. Additional exposure to the sharp blade occurs when loading a new blade and re-clamping it in position.

U.S. Patent No. 3,667,330 (Kobernick) discloses an automated microtome assembly which includes a continuous flexible steel blade whose ends are mounted upon feed and takeup reels for intermittent motor-driven advancement to enable advancement

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of new cutting surface without contact by a user. The changing of the knife edge may be actuated manually or automatically. The '330 patent does not disclose a method or apparatus for the changing of individual blades, or provide safety features for the changing of the blade.

5 U.S. Patent 4,207,790 (Endo) is directed to a knife holder and blade cassette for microtomes. The knife holder comprises a base plate and a holder plate for holding the knife edge onto the base plate. The blade cartridge is spring-loaded for biasing the blades upwardly towards the exit from the cartridge. To replace a blade, the user must first  
10 loosen the bolts holding the knife holder plate down, then engage the cartridge with the edge of the knife holder assembly, and finally slide a new blade out of the cartridge and into contact with the dull blade, thereby positioning a new blade beneath the holder plate and simultaneously pushing the dull blade out of position. There is no disclosure related to automation of the process, what happens to the spent blade, or safety features.

Blade changers for hand-held shavers are known. U.S. Patent 1,817,512  
15 (Gaisman) and 2,741,837 (Breazeale) disclose a cartridge containing individual blades wherein the blade is manually dispensed from the cartridge using an ejector, and at the end of the ejector stroke the blade is located in the cutting position, and the used blade is received in a take-up cartridge (see Gaisman, Fig. 11). U.S. Patent 2,653,379 (Austin) discloses a box with a cartridge on either side of a razor. A slider pushes a new blade  
20 from the first cartridge onto the razor, which pushes the used blade into the second cartridge. U.S. Patent 2,679,685 (Austin) discloses a razor blade changer where advancing a pusher causes a blade in supply cartridge C to advance into the razor and push the used blade out into take-up cartridge D. When cartridge C is empty, it is put in place of discarded cartridge D to act as the new take-up cartridge, and a full supply  
25 cartridge is put in place of cartridge C.

Patents on razor blade containers include US Patent 2,592,138 (Gwoosh et al.) for a razor blade package which teaches the use of a coil spring to bias blades towards the dispenser opening of a blade container. The top has a thumb opening to allow manual advance of the blades. US Patent 2,604,979 (Roberts) shows a spring-loaded blade  
30 container which uses a leaf-spring. US Patent 2,775,366 (Willhelm) discloses the use of a compression spring to urge a plurality of blades towards the package opening. US

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Patent 5,409,133 (Gringer) is a spring-loaded blade dispenser wherein the entire top except guide rails, is open for application of a manual dispensing force. The dispenser is also capable of receiving spent blades back through a disposal opening 34 (see Figs. 9-10). None of the above mentioned patents are adapted for automatic use.

- 5           There is a need for an automated microtome blade changing system that safeguards the user against being seriously injured, and enhances the work flow in the pathology laboratory.

### Summary of the Invention

- 10           The invention is directed to an automated rotary microtome blade changing apparatus, comprising an upper stage adapted to releasably engage a supply and a waste cartridge, the upper stage having a loading segment adapted to engage and move blades contained within said supply cartridge into a cutting position; clamping means for releasably holding the blades in place for cutting operations; power means for driving the  
15           movement of blades and clamping mechanisms; and electronic control means for integrating all of the functions of the apparatus.

- The invention is also directed to an automated rotary microtome blade changing apparatus, comprising an upper stage adapted to releasably engage a supply and a waste cartridge, the upper stage having a reverser shuttle adapted to engage and move blades  
20           contained within said supply cartridge into a cutting position; clamping means for releasably holding the blades in place for cutting operations; power means for driving the movement of blades and clamping mechanisms; and electronic control means for integrating all of the functions of the apparatus.

- Also described herein is an improved blade supply cartridge wherein the cartridge  
25           comprises a body, a spring, a dispensing tab, and blades, wherein the improvement comprises a toothed portion on said dispensing tab adapted to engage mating gear teeth on said blade changer.

- Also described herein is an improved blade supply cartridge wherein the cartridge comprises a body, a spring, a dispensing tab, and blades, wherein the improvement  
30           comprises a touch memory device in contact with the cartridge, the touch memory device programmed to contain content information relating to said cartridge.



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It is an object of the present invention to provide a fully automated blade changer for the histopathology laboratory that reduces and hopefully eliminates the chances of being cut accidentally during routine laboratory operations with the microtome blades.

It is another object of the present invention to provide a new blade cartridge that, in cooperation with a microcontroller in the blade changer, can track blade useage and signal the user when blades are running low.

These and other advantages of the present invention will become clear in the following description of the invention.

#### **Brief Description of the Drawings**

Figure 1 is a front elevational view of the automated blade changer with both the upper and lower stages shown.

Figure 2 is a front elevational view with partial cutaway of the upper stage of the device.

Figures 3A-3D show, respectively, a perspective view of a blade supply cartridge, a top view of the same, a sectional view along lines C-C shown in 3B, and a blade adapted for use with the invention.

Figures 4A-D are front elevational views of the sequence of positions that a blade typically arrives at during loading.

Figures 5A-C are, respectively, a front elevational perspective view of a dedicated waste cartridge, a top view of the same, and a sectional view along lines D-D.

Figure 6 is a block diagram of the electronics controlling the blade changer.

Figure 7 is a front elevational view of the second embodiment of the automated blade changer with both upper and lower stages shown. A cutout shows the drive shaft gearing arrangement.

Figure 8 is a front elevational view of the second embodiment of the automated blade changer with partial cutaway of the upper stage of the device.

#### **Description of the Preferred Embodiments**

The purpose of this invention is to improve the safety and productivity of the process of cutting tissue blocks with a rotary microtome. It is achieved by automating the

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process of loading new knife blades into the microtome and disposing of used ones. At present, cutting tissue on a microtome involves considerable handling of disposable knife blades with the technologist's bare hand. So, because the edge of the blade is razor sharp, cutting injuries are common. This risk of injury is significant even if the technologist  
5 only comes into contact with a blade twice – once to load, once to discard – but current practice in histotechnology often greatly increases this exposure.

There are two other problems the invention ameliorates. First, with constant handling of the blade also comes a risk of infection from the tissue. With properly processed tissue there is no risk of infection, but it is possible with non-processed or  
10 under-processed tissue that direct contact with the tissue can lead to infection. Therefore, by eliminating all physical contact with the blade, the risk of infection is significantly reduced. Secondly, the process of loading and unloading the blades by hand is somewhat time-consuming. The invention addresses this issue as well, by replacing the manual movement of blades with an automated movement of blades.

15 Thus, this invention offers to the histology laboratory increased safety, flexibility and efficiency. These features all translate to the laboratory's financial bottom line: safety translates to fewer missed work days and enhanced risk management, while flexibility and efficiency allow the laboratory to provide a maximum output of staining results with a minimum number of laboratory technicians.

20 The invention is best illustrated by reference to the following Figures 1-2. The preferred embodiments are based on a standard knife stage design. That is, the invention is contained within the upper stage body of a standard rotary microtome knife holder. In Figures 1 and 2, the upper stage body 5 is the platform for the functional portions of the blade changer apparatus. It contains the major sub-components of the blade changer,  
25 including waste and supply blade cartridges 10, 15, respectively, clamping means, blade 100, power means and electronic control means. A general overview of the device follows, with more particularity in subsequent sections.

#### I. General overview

30 A first embodiment of the blade changer comprises lower and upper stage bodies 1, 5, respectively. With reference to Fig. 1 the microtome blade cartridges are removably

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located within the upper stage body 5. The lower stage body is adaptable to a wide variety of rotary microtomes, and serves as the common interface mounting for the upper stage. The disposable blade cartridges 10, 15 are adapted to lock into the upper stage body 5 so as to provide an element of safety. The cartridges are described more fully below and in Figs. 3-5. They are releasable only when the individual blades are fully secured within the body of the cartridge. This "interlock" function can be attained in many ways, however a preferred embodiment includes an on-board microcontroller which monitors the state of operation of the blade changer. When the controller's logic functions determine that no blade edges are exposed, then the clamping plate and/or the cartridges may be released. The interlock function is more fully described below. The clamping means includes clamping plate 20, support plate 25, and clamp pivot rod 112 which together function to clamp the blade in the cutting position during use of the blade in the microtome. Loading segment 30 has a toothed gear portion rotatably mounted to engage the reciprocal teeth on dispensing tab 90. Dispensing tab 90 is integral with the supply cartridge. At a second end of the supply cartridge loading segment 30 engages loading cam 40 (Fig. 2). The function of loading segment 30 is to move dispensing tab 90 of the blade supply cartridge 15 thereby urging new blades 95 to the central cutting area. This is performed through downwardly protruding member 92 which engages a slot or hole 96 formed in the body of blade 95 (See Fig. 3) which enables dispensing tab 90 to engage the topmost blade in its stored position at the top of the stack of blades contained within supply cartridge 15. Loading cam 40 engages with the lower extending portion 32 of loading segment 30 through the groove in the surface of loading cam 40 thereby enabling rotation of loading segment 30 around shoulder screw 35. Shoulder screw 35 is anchored into upper stage body 5 and its function is to provide a pivot for loading segment 30.

Power means comprises bidirectional DC motor 50 which drives the motor gear 55, which in turn drives the drive shaft gear 60. The purpose of the motor, gear and pulley is to rotate drive shaft 65 and thus provide the power for moving loading segment 30 from left to right, and/or from right to left; and simultaneously moving clamping plate 20 forward and backward in order to either clamp or release a blade in the cutting area. The motor is bidirectional so that clamp pivot rod 112 may be released only when the

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motor is reversed. This function would require a clutch mechanism that in forward (normal) operation engages a groove in the rod, which stops the rod from being removed from the blade changer. Since removal of the rod is a precursor to removal of the clamping plate for cleaning access, this is another safety interlock feature of the device.

5       The loading cam 40 and clamping cam 45 are coordinated so that loading segment 30 can only push a new blade 95 into position when clamping plate 20 is open (pressure relieved from the blade). It is well within the skill in the art to design and position the two cams to effectuate this coordinated function. Electronic control means includes a printed circuit board 70 which contains the microcontroller and associated circuits and  
10       controls the operation of the blade changer, push-button switches 76, 77 on keypad 75, a power source 85, and safety interlocks 155. The "blade advance" signal comes to the electronic circuit from keypad 75 via blade advance switch 76. In a preferred embodiment the power for the blade changer is supplied from the on-board battery 86. Alternatively, power could be supplied from an AC source (not shown).

15       A second embodiment of the automated blade changer is depicted in Figures 7 and 8. The primary difference in this second embodiment is that loading segment 30 and the attendant gearing for it have been replaced with a reverser screw 240 and reverser shuttle 230 combination. The dispensing tab on the supply cartridge has also been modified to adapt to the shuttle. The advantages include less coordination of the motion because the  
20       shuttle reverses direction automatically as the drive shaft continues in a unidirectional fashion.

## II. Detailed Description of the Invention

      The clamping means includes clamping plate 20, support plate 25, and clamp  
25       pivot rod 112 which together function to clamp the blade in the cutting position during use of the blade in the microtome. Support plate 25 has a thin rectangular block 27 attached on its surface which provides a ledge upon which blades in the cutting area sit. In a preferred embodiment, the ledge can be magnetized which aids in retention of the blade on the support plate. Alternatively, a ledge could be machined into its surface to  
30       provide the same support function. Clamping cam 45 engages clamping plate 20 on leaf spring 22 so that when the cam is turned, clamping plate 20 releasably engages support

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plate 25, thus holding or releasing blade 100. A clamp pivot rod 112 provides a pivot point about which the clamp pivots. The rod may pass through a hole or tunnel in the plate or it may be mounted directly behind the plate. In a preferred embodiment, the rod passes through the block 21 securely attached to the plate. The rod is anchored to the upper stage body 5 at both ends through holes adapted for receiving the rod (not shown). Other clamping means come within the spirit and scope of the invention, which are not explicitly taught herein, but which are equivalent in function to those presented herein. For instance, it is possible to use a manual clamp to attain the similar results, albeit with a loss in automation of the entire procedure. Another preferred embodiment would utilize a servo motor directly moving the clamp, replacing clamping cam 45.

Electronic control means are depicted schematically in Fig. 6. It includes a printed circuit board 70 (Fig. 2) mounted below the key pad which contains the microcontroller and controls the operation of the blade changer. In a preferred embodiment, the electronic controls are on-board, but alternatively they may be contained in an instrument housing separate from the blade changer. A suitable microcontroller for driving the operations of the blade changer is selected from the PIC family of microcontrollers, manufactured by Microchip, Inc., Chandler, AZ. One of ordinary skill in the electronic arts is able to select and implement an individual PIC controller for these purposes. The "blade advance" signal comes to the microcontroller circuit from user-activated push-button switch located on keypad 75, also a part of the control means. In a preferred embodiment the power for the blade changer is supplied from the on-board battery 86. Alternatively, power could be supplied from an AC adapter. The electronic control means also enables the interlock function. The safety interlock feature hardware includes a touch memory device 150 (also known as a "data button") mounted on a blade cartridge, the microcontroller, touch memory reader, and electronically-controlled locking mechanisms for the cartridges 10, 15. The interlock function is described in more detail below.

Disposable microtome blade cartridges are described herein with new and useful advantages. As shown in cross-section C-C (Fig. 3C), supply cartridge 15 comprises a body 105, having sides 110, 115, and a top portion 120 having a groove or slot 125 adapted for receiving rail portion 130 of dispensing tab 90. Sides 110 and 115 each have

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a guide slot 117 machined into them for engaging cartridge guides 119. In a preferred embodiment the guides are rod-shaped and are mounted to the upper stage and are positioned so that when a cartridge engages the guides it is correctly positioned relative to the support plate 25 and the loading segment 30. Spring 107 is contained within body 105 and serves to urge the blade stack 135 upwardly towards the blade exit 140. Any conventional spring type may be used, including leaf springs, helical springs, and even a spring member integral to the body 105, such as a molded plastic tab. A touch memory device 150 is attached to the cartridge and contains the information pertaining to the contents of the cartridge, such as the number of blades, type, lot number, expiration, and related information. The touch memory device enables communication between the cartridge and the blade changer, thus adding an element of intelligence to the blade changer.

The supply cartridge may also serve to function as a waste cartridge for accepting spent blades. Again with reference to Fig. 3C, cross-section C-C shows an entrance 145 for used blades. The supply cartridge is oriented on upper stage body 5 in reverse so that entrance 145 receives spent blades as they are pushed out of the cutting position by a new blade. As the user continues to load new blades, used blades accumulate in the reversed supply cartridge now functioning as a waste cartridge. Spring 107 will be pushed towards the top 120 of the cartridge as waste blades accumulate. The microcontroller will signal the user that the waste cartridge is filled when the microcontroller has recorded the maximum number of allowable blades. Alternatively, a dedicated waste cartridge is also possible, and is depicted in Figs. 5A-C.

Again with reference to Fig. 3, supply cartridge 15 has a dispensing tab 90 integral with the cartridge and adapted for engaging each new blade 95. Downward protrusion 92 engages a slot or opening in each new blade. The downward protrusion may be a metal tab, a plastic hook or similar equivalent article. The main design limitation is that it reliably contact only one blade at a time. Downward protrusion 92 may be located anywhere on dispensing tab 90 so long as it functions to urge a single blade out of the cartridge for each cycle of the loading segment 30. In the preferred embodiment shown in Fig. 3, the protrusion is forward mounted on the blade side of dispensing tab 90. A second embodiment of the dispensing tab is shown in Figs. 7-8.

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The primary feature is that dispensing tab shown (290) is designed with a slot or cutout for engaging shuttle tab 231. It does not have the teeth necessary for engaging the loading segment 30, which is not present in this embodiment.

The safety interlock feature will now be described with more particularity. The safety interlock feature includes touch memory device 150 mounted on the cartridge (Figs. 3A-3B, 7-8), an on-board PIC microcontroller contained within the blade changer for running the operations of the device while being in communication with the touch memory device, a contact reader (not shown) for the data button, and electronically-controlled locking mechanisms for the cartridges. The touch memory device is described in U.S. Patent Number 6,045,759, filed December 19, 1997 and issued April 4, 2000, incorporated herein by reference in its entirety. In a preferred embodiment, the memory device is an EPROM such as the Dallas Semiconductor DS1985 F5 16 Kbit add-only touch memory device. Its primary function is to initialize the safety interlock system for each new blade cartridge that is presented to the blade changer. The touch memory device contains information such as the number of blades, date of expiration, lot no., etc. In operation, the touch memory device is initially read-in the number of blades in the cartridge when loaded with blades at the factory. When the cartridge is loaded into the supply position on the blade changer, contacts on the cartridge connected to the touch memory device, or the touch memory device itself, make electrical contact with a touch memory reader (not shown) which is built into the upper stage so that as the cartridge seats itself it contacts the touch memory reader. The on-board microcontroller then tracks the position and number of blades left in the cartridge until the cartridge is empty. The on-board microcontroller will then notify the user through an interface such as LEDs or LCD readout. The on-board microcontroller executes the blade loading functions and maintains a look-up table that correlates blade position with steps executed, and so it tracks where the blades are at all times, and most importantly, whether blades are outside of the cartridges (and a potential safety hazard). If they are, then the interlock function will not allow the cartridges to be removed until the blades are within their respective cartridges. Safety interlocks 155 (Figs, 2, 8) are mechanical- or solenoid-operated latches or arms that retain the cartridge in position, until activated

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by the microcontroller to release the cartridge. A hole or other ledge for the latch to attach to is located on the cartridge on the side facing the upper stage.

The cycle portion of the operation of the blade changer will now be described, with particular reference to Figs. 2 and 4. Starting with loading a new blade cartridge, a new supply cartridge 15 is loaded into the upper stage body 5, and locks into position. To eject a new blade 95 from supply cartridge 15, the user presses the blade advance push-button 76 on key pad 75. Switch 76 is in electrical communication with the microcontroller which then activates motor 50. Motor 50 actuates driving gear 55 and gear 60 which cause rotation of drive shaft 65. This action then causes the loading and clamping cams 40 and 45, respectively, to move in fixed relation with each other. These cams are oriented on the drive shaft so that the clamping cam 45 is not engaged with the clamping plate 20 for the first half-turn of drive shaft 65 while loading cam 40 is moving loading segment 30 from right to left and consequently dispensing tab 90 moves the first part of the new blade into the cutting area.

During the second half-turn of drive shaft 65 clamping cam 45 engages with clamping plate 20 causing the blade to be clamped in the cutting position while the loading cam 40 moves the loading segment 30 and the dispensing tab 90 from left to right. In the middle of this move the microcontroller stops motor 50 and the blade 95 stays clamped ready for cutting.

When the new blade 95 is pushed from the supply cartridge 15 to the cutting area it pushes the used blade from the cutting area to waste cartridge 10. This design allows partial movement of the new blade 95 in one direction (1/3 of a blade width with each back-and-forth cycle of the loading segment), in order to maximize use of the blade for small tissue blocks. It takes three full cycles of the dispensing tab to fully eject and position new blade 95. More particularly and with reference to Figs. 4A-4D, Fig. 4A shows the supply cartridge 15 at rest with the new blade 95 concealed from view within the cartridge (start position). As loading segment 30 (not shown in this view) is activated, it engages the teeth on dispensing tab 90 which then pushes new blade 95 one third of its length out of the housing (Fig. 4B). As loading cam 40 rotates, the direction of dispensing tab 90 is then reversed by loading segment 30, and the tab moves back to its starting position. The second cycle repeats the left-right motion of the dispensing tab,



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pushing the blade yet another one-third of its length (Figs. 4C and 4D) per cycle. Fig. 4D shows a fully ejected new blade 95. Clearly an alternative embodiment which pushes the blade out a different fraction of its length, such as  $\frac{1}{4}$ , or  $\frac{1}{5}$ , is also within the spirit and scope of this invention.

5 Referring again to Fig. 2, the used blade 95 is pushed out of its cutting position by the action of the new blade 95 being urged out of the supply cartridge, as previously described. The two blades occupy the same plane, and so as a new blade is ejected, it engages the old blade at their common edges. The used blade is pushed into waste cartridge 10, which may be an empty supply cartridge adapted to fit into upper stage body 5 (Fig. 5), or it may be an empty supply cartridge being reversible and having an entrance 145, as previously described. In an alternate embodiment, a dedicated waste cartridge may be used. In Figs. 5A-C, such a cartridge is shown. It shares many of the same components as the supply cartridge.

15 A second embodiment of the blade changer comprises lower and upper stage bodies 201, 205, respectively. With reference to Figs. 7-8, the microtome blade cartridges are removably located within the upper stage body 205. The lower stage body is adaptable to a wide variety of rotary microtomes, and serves as the common interface mounting for the upper stage. The disposable blade cartridges 210, 215 are adapted to lock into the upper stage body 205 so as to provide an element of safety. The cartridges are described more fully in the first embodiment and in Figs. 3-5. In this second embodiment they differ only in that the dispensing tab 90 (Figs. 1-2) is replaced by dispensing tab 290 (Fig. 7-8). The cartridges are releasable only when the individual blades are fully secured within the body of the cartridge. This "interlock" function can be attained in many ways, however a preferred embodiment includes an on-board microcontroller which monitors the state of operation of the blade changer. When the controller's logic functions determine that no blade edges are exposed, then the clamping plate and/or the cartridges may be released. The interlock function is more fully described below. The clamping means includes clamping plate 20, support plate 25, and clamp pivot rod 112 which together function to clamp the blade in the cutting position during use of the blade in the microtome. Reverser shuttle 230 has a shuttle tab portion 231 mounted to engage the slot 292 in dispensing tab 290. Dispensing tab 290 is

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integral with the supply cartridge 215. Reverser shuttle 230 has a threaded portion (not shown) which engages reverser screw 240. The function of reverser shuttle 230 is to move dispensing tab 290 of the blade supply cartridge 215 thereby urging new blades 95 to the central cutting area. As shown by Figs 3-4, this is performed through downwardly protruding member 92 which engages a slot or hole 96 formed in the body of blade 95 which enables dispensing tab 290 to engage the topmost blade in its stored position at the top of the stack of blades contained within supply cartridge 215. Reverser screw 240 is supported on either end by bearings 241 which are supported and retained by upper stage body 205. Reverser shuttle 230 engages reverser screw 240 through helical cutout 232 and mating helical threads (not shown) located on the shuttle 230. In a preferred embodiment, reverser shuttle 230 acts like a threaded nut and moves laterally at the urging of reverser screw 230. The helical cutout of reverser screw 230 is unique in that the reverser shuttle will move back and forth without a concomitant change in direction of any other component in the drive train. Similar reverser screws are common and well-known in the ink-jet printer art.

Power means comprises bidirectional DC motor 250 which rotates drive shaft 265 and drive gear 255, which in turn engages reverser screw gear 260. Reverser screw gear 260 in turn is attached to reverser screw 240, and when rotational motion is applied through drive shaft 265 the result is rotational motion in reverser screw 240, and thus the threads of reverser shuttle 230 will be urged to move laterally along the helical cutout. Drive shaft 265 also simultaneously moves clamping plate 20 forward and backward in order to either clamp or release a blade in the cutting area. The motor is bidirectional so that clamp pivot rod 112 may be released only when the motor is reversed. This function would require a clutch mechanism that in forward (normal) operation engages a groove in the rod, which stops the rod from being removed from the blade changer. Since removal of the rod is a precursor to removal of the clamping plate for cleaning access, this is another safety interlock feature of the device.

The reverser screw 240 and clamping cam 45 are coordinated so that reverser shuttle 230 can only push a new blade 95 into position when clamping plate 20 is open (pressure relieved from the blade). It is well within the skill in the art to design and position the two cams to effectuate this coordinated function.

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The functional advantages of the invention described above are numerous. First, the blades are moved into the cutting area completely without manual contact. Second, blades are moved into the waste cartridge for disposal completely without manual contact. Third, moving the blades automatically, by push-button switch or by manual  
5 lever, is a fast, efficient way to load and unload.

Although certain presently preferred embodiments of the invention have been described herein, it will be apparent to those skilled in the art to which the invention pertains that variations and modifications of the described embodiment may be made without departing from the spirit and scope of the invention. Accordingly, it is intended  
10 that the invention be limited only to the extent required by the appended claims and the applicable rules of law.

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### Related Applications

This application is a continuation-in-part of commonly assigned U.S. Serial Number 09/562,270, filed April 29, 2000.

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### Background

#### 1. Field of the Invention

The present invention is directed to apparatus for use in preparing tissue sections for use in diagnostic histopathology and, more particularly, to an apparatus that automatically changes the blades of a microtome without exposure of the user to the cutting edges of the blades.

10

#### 2. Description of Related Art

Microtomes have been used for many years to meet the exacting requirements necessary for thin sectioning of paraffin-embedded tissue. Essentially, microtomes are holders for razor-sharp metal blades, against which a block of paraffin-embedded tissue is moved in an up-and-down motion. Concurrently, either the tissue block is advanced against the blade, or vice versa, so that with each up or down stroke, a thin slice or "section" of tissue is cut from the block. The blades are highly engineered for the precise requirements of tissue sectioning. Specifically, the blades are capable of cutting sections as thin as 1  $\mu\text{m}$ .

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The present practice for tissue sectioning requires the blades be changed as they become dulled. This necessitates alleviating the pressure that the blade holder puts on the blade to keep it in place, usually by removing a clamping mechanism. Once the clamp is removed, the blade can be lifted off of the rest. Usually, this is accomplished by grasping the blade at an edge and discarding it in a sharps container, all of which is done by hand. This exposed the user to the edges of the blade, and of course the potential of serious injury. Additional exposure to the sharp blade occurs when loading a new blade and re-clamping it in position.

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U.S. Patent No. 3,667,330 (Kobernick) discloses an automated microtome assembly which includes a continuous flexible steel blade whose ends are mounted upon feed and takeup reels for intermittent motor-driven advancement to enable advancement

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of new cutting surface without contact by a user. The changing of the knife edge may be actuated manually or automatically. The '330 patent does not disclose a method or apparatus for the changing of individual blades, or provide safety features for the changing of the blade.

5 U.S. Patent 4,207,790 (Endo) is directed to a knife holder and blade cassette for microtomes. The knife holder comprises a base plate and a holder plate for holding the knife edge onto the base plate. The blade cartridge is spring-loaded for biasing the blades upwardly towards the exit from the cartridge. To replace a blade, the user must first  
10 loosen the bolts holding the knife holder plate down, then engage the cartridge with the edge of the knife holder assembly, and finally slide a new blade out of the cartridge and into contact with the dull blade, thereby positioning a new blade beneath the holder plate and simultaneously pushing the dull blade out of position. There is no disclosure related to automation of the process, what happens to the spent blade, or safety features.

Blade changers for hand-held shavers are known. U.S. Patent 1,817,512  
15 (Gaisman) and 2,741,837 (Breazeale) disclose a cartridge containing individual blades wherein the blade is manually dispensed from the cartridge using an ejector, and at the end of the ejector stroke the blade is located in the cutting position, and the used blade is received in a take-up cartridge (see Gaisman, Fig. 11). U.S. Patent 2,653,379 (Austin) discloses a box with a cartridge on either side of a razor. A slider pushes a new blade  
20 from the first cartridge onto the razor, which pushes the used blade into the second cartridge. U.S. Patent 2,679,685 (Austin) discloses a razor blade changer where advancing a pusher causes a blade in supply cartridge C to advance into the razor and push the used blade out into take-up cartridge D. When cartridge C is empty, it is put in place of discarded cartridge D to act as the new take-up cartridge, and a full supply  
25 cartridge is put in place of cartridge C.

Patents on razor blade containers include US Patent 2,592,138 (Gwoosh et al.) for a razor blade package which teaches the use of a coil spring to bias blades towards the dispenser opening of a blade container. The top has a thumb opening to allow manual advance of the blades. US Patent 2,604,979 (Roberts) shows a spring-loaded blade  
30 container which uses a leaf-spring. US Patent 2,775,366 (Willhelm) discloses the use of a compression spring to urge a plurality of blades towards the package opening. US

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Patent 5,409,133 (Gringer) is a spring-loaded blade dispenser wherein the entire top except guide rails, is open for application of a manual dispensing force. The dispenser is also capable of receiving spent blades back through a disposal opening 34 (see Figs. 9-10). None of the above mentioned patents are adapted for automatic use.

- 5           There is a need for an automated microtome blade changing system that safeguards the user against being seriously injured, and enhances the work flow in the pathology laboratory.

### Summary of the Invention

- 10           The invention is directed to an automated rotary microtome blade changing apparatus, comprising an upper stage adapted to releasably engage a supply and a waste cartridge, the upper stage having a loading segment adapted to engage and move blades contained within said supply cartridge into a cutting position; clamping means for releasably holding the blades in place for cutting operations; power means for driving the  
15           movement of blades and clamping mechanisms; and electronic control means for integrating all of the functions of the apparatus.

- The invention is also directed to an automated rotary microtome blade changing apparatus, comprising an upper stage adapted to releasably engage a supply and a waste cartridge, the upper stage having a reverser shuttle adapted to engage and move blades  
20           contained within said supply cartridge into a cutting position; clamping means for releasably holding the blades in place for cutting operations; power means for driving the movement of blades and clamping mechanisms; and electronic control means for integrating all of the functions of the apparatus.

- Also described herein is an improved blade supply cartridge wherein the cartridge  
25           comprises a body, a spring, a dispensing tab, and blades, wherein the improvement comprises a toothed portion on said dispensing tab adapted to engage mating gear teeth on said blade changer.

- Also described herein is an improved blade supply cartridge wherein the cartridge comprises a body, a spring, a dispensing tab, and blades, wherein the improvement  
30           comprises a touch memory device in contact with the cartridge, the touch memory device programmed to contain content information relating to said cartridge.

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It is an object of the present invention to provide a fully automated blade changer for the histopathology laboratory that reduces and hopefully eliminates the chances of being cut accidentally during routine laboratory operations with the microtome blades.

It is another object of the present invention to provide a new blade cartridge that, in cooperation with a microcontroller in the blade changer, can track blade useage and signal the user when blades are running low.

These and other advantages of the present invention will become clear in the following description of the invention.

#### **Brief Description of the Drawings**

Figure 1 is a front elevational view of the automated blade changer with both the upper and lower stages shown.

Figure 2 is a front elevational view with partial cutaway of the upper stage of the device.

Figures 3A-3D show, respectively, a perspective view of a blade supply cartridge, a top view of the same, a sectional view along lines C-C shown in 3B, and a blade adapted for use with the invention.

Figures 4A-D are front elevational views of the sequence of positions that a blade typically arrives at during loading.

Figures 5A-C are, respectively, a front elevational perspective view of a dedicated waste cartridge, a top view of the same, and a sectional view along lines D-D.

Figure 6 is a block diagram of the electronics controlling the blade changer.

Figure 7 is a front elevational view of the second embodiment of the automated blade changer with both upper and lower stages shown. A cutout shows the drive shaft gearing arrangement.

Figure 8 is a front elevational view of the second embodiment of the automated blade changer with partial cutaway of the upper stage of the device.

#### **Description of the Preferred Embodiments**

The purpose of this invention is to improve the safety and productivity of the process of cutting tissue blocks with a rotary microtome. It is achieved by automating the

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process of loading new knife blades into the microtome and disposing of used ones. At present, cutting tissue on a microtome involves considerable handling of disposable knife blades with the technologist's bare hand. So, because the edge of the blade is razor sharp, cutting injuries are common. This risk of injury is significant even if the technologist  
5 only comes into contact with a blade twice – once to load, once to discard – but current practice in histotechnology often greatly increases this exposure.

There are two other problems the invention ameliorates. First, with constant handling of the blade also comes a risk of infection from the tissue. With properly processed tissue there is no risk of infection, but it is possible with non-processed or  
10 under-processed tissue that direct contact with the tissue can lead to infection. Therefore, by eliminating all physical contact with the blade, the risk of infection is significantly reduced. Secondly, the process of loading and unloading the blades by hand is somewhat time-consuming. The invention addresses this issue as well, by replacing the manual movement of blades with an automated movement of blades.

15 Thus, this invention offers to the histology laboratory increased safety, flexibility and efficiency. These features all translate to the laboratory's financial bottom line: safety translates to fewer missed work days and enhanced risk management, while flexibility and efficiency allow the laboratory to provide a maximum output of staining results with a minimum number of laboratory technicians.

20 The invention is best illustrated by reference to the following Figures 1-2. The preferred embodiments are based on a standard knife stage design. That is, the invention is contained within the upper stage body of a standard rotary microtome knife holder. In Figures 1 and 2, the upper stage body 5 is the platform for the functional portions of the blade changer apparatus. It contains the major sub-components of the blade changer,  
25 including waste and supply blade cartridges 10, 15, respectively, clamping means, blade 100, power means and electronic control means. A general overview of the device follows, with more particularity in subsequent sections.

#### I. General overview

30 A first embodiment of the blade changer comprises lower and upper stage bodies 1, 5, respectively. With reference to Fig. 1 the microtome blade cartridges are removably



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located within the upper stage body 5. The lower stage body is adaptable to a wide variety of rotary microtomes, and serves as the common interface mounting for the upper stage. The disposable blade cartridges 10, 15 are adapted to lock into the upper stage body 5 so as to provide an element of safety. The cartridges are described more fully below and in Figs. 3-5. They are releasable only when the individual blades are fully secured within the body of the cartridge. This "interlock" function can be attained in many ways, however a preferred embodiment includes an on-board microcontroller which monitors the state of operation of the blade changer. When the controller's logic functions determine that no blade edges are exposed, then the clamping plate and/or the cartridges may be released. The interlock function is more fully described below. The clamping means includes clamping plate 20, support plate 25, and clamp pivot rod 112 which together function to clamp the blade in the cutting position during use of the blade in the microtome. Loading segment 30 has a toothed gear portion rotatably mounted to engage the reciprocal teeth on dispensing tab 90. Dispensing tab 90 is integral with the supply cartridge. At a second end of the supply cartridge loading segment 30 engages loading cam 40 (Fig. 2). The function of loading segment 30 is to move dispensing tab 90 of the blade supply cartridge 15 thereby urging new blades 95 to the central cutting area. This is performed through downwardly protruding member 92 which engages a slot or hole 96 formed in the body of blade 95 (See Fig. 3) which enables dispensing tab 90 to engage the topmost blade in its stored position at the top of the stack of blades contained within supply cartridge 15. Loading cam 40 engages with the lower extending portion 32 of loading segment 30 through the groove in the surface of loading cam 40 thereby enabling rotation of loading segment 30 around shoulder screw 35. Shoulder screw 35 is anchored into upper stage body 5 and its function is to provide a pivot for loading segment 30.

Power means comprises bidirectional DC motor 50 which drives the motor gear 55, which in turn drives the drive shaft pulley-gear 60. The purpose of the motor, gear and pulley is to rotate drive shaft 65 and thus provide the power for moving loading segment 30 from left to right, and/or from right to left; and simultaneously moving clamping plate 20 forward and backward in order to either clamp or release a blade in the cutting area. The motor is bidirectional so that clamp pivot rod 112 may be released only

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when the motor is reversed. This function would require a clutch mechanism that in forward (normal) operation engages a groove in the rod, which stops the rod from being removed from the blade changer. Since removal of the rod is a precursor to removal of the clamping plate for cleaning access, this is another safety interlock feature of the device.

The loading cam 40 and clamping cam 45 are coordinated so that loading segment 30 can only push a new blade 95 into position when clamping plate 20 is open (pressure relieved from the blade). It is well within the skill in the art to design and position the two cams to effectuate this coordinated function. Electronic control means includes a printed circuit board 70 which contains the microcontroller and associated circuits and controls the operation of the blade changer, push-button switches 76, 77 on keypad 75, a power source 85, and safety interlocks 155. The "blade advance" signal comes to the electronic circuit from keypad 75 via blade advance switch 76. In a preferred embodiment the power for the blade changer is supplied from the on-board battery 86. Alternatively, power could be supplied from an AC source (not shown).

A second embodiment of the automated blade changer is depicted in Figures 7 and 8. The primary difference in this second embodiment is that loading segment 30 and the attendant gearing for it have been replaced with a reverser screw 240 and reverser shuttle 230 combination. The dispensing tab on the supply cartridge has also been modified to adapt to the shuttle. The advantages include less coordination of the motion because the shuttle reverses direction automatically as the drive shaft continues in a unidirectional fashion.

## II. Detailed Description of the Invention

The clamping means includes clamping plate 20, support plate 25, and clamp pivot rod 112 which together function to clamp the blade in the cutting position during use of the blade in the microtome. Support plate 25 has a thin rectangular block 27 attached on its surface which provides a ledge upon which blades in the cutting area sit. In a preferred embodiment, the ledge can be magnetized which aids in retention of the blade on the support plate. Alternatively, a ledge could be machined into its surface to provide the same support function. Clamping cam 45 engages clamping plate 20 on leaf

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spring 22 so that when the cam is turned, clamping plate 20 releasably engages support plate 25, thus holding or releasing blade 100. A clamp pivot rod 112 provides a pivot point about which the clamp pivots. The rod may pass through a hole or tunnel in the plate or it may be mounted directly behind the plate. In a preferred embodiment, the rod passes through the block 21 securely attached to the plate. The rod is anchored to the upper stage body 5 at both ends through holes adapted for receiving the rod (not shown). Other clamping means come within the spirit and scope of the invention, which are not explicitly taught herein, but which are equivalent in function to those presented herein. For instance, it is possible to use a manual clamp to attain the similar results, albeit with a loss in automation of the entire procedure. Another preferred embodiment would utilize a servo motor directly moving the clamp, replacing clamping cam 45.

Electronic control means are depicted schematically in Fig. 6. It includes a printed circuit board 70 (Fig. 2) mounted below the key pad which contains the microcontroller and controls the operation of the blade changer. In a preferred embodiment, the electronic controls are on-board, but alternatively they may be contained in an instrument housing separate from the blade changer. A suitable microcontroller for driving the operations of the blade changer is selected from the PIC family of microcontrollers, manufactured by Microchip, Inc., Chandler, AZ. One of ordinary skill in the electronic arts is able to select and implement an individual PIC controller for these purposes. The "blade advance" signal comes to the microcontroller circuit from user-activated push-button switch located on keypad 75, also a part of the control means. In a preferred embodiment the power for the blade changer is supplied from the on-board battery 86. Alternatively, power could be supplied from an AC adapter. The electronic control means also enables the interlock function. The safety interlock feature hardware includes a touch memory device 150 (also known as a "data button") mounted on a blade cartridge, the microcontroller, touch memory reader, and electronically-controlled locking mechanisms for the cartridges 40 10, 15. The interlock function is described in more detail below.

Disposable microtome blade cartridges are described herein with new and useful advantages. As shown in cross-section C-C (Fig. 3C), supply cartridge 15 comprises a body 105, having sides 110, 115, and a top portion 120 having a groove or slot 125

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adapted for receiving rail portion 130 of dispensing tab 90. Sides 110 and 115 each have a guide slot 117 machined into them for engaging cartridge guides 119. In a preferred embodiment the guides are rod-shaped and are mounted to the upper stage and are positioned so that when a cartridge engages the guides it is correctly positioned relative to the support plate 25 and the loading segment 30. Spring 107 is contained within body 105 and serves to urge the blade stack 135 upwardly towards the blade exit 140. Any conventional spring type may be used, including leaf springs, helical springs, and even a spring member integral to the body 105, such as a molded plastic tab. A touch memory device 150 is attached to the cartridge and contains the information pertaining to the contents of the cartridge, such as the number of blades, type, lot number, expiration, and related information. The touch memory device enables communication between the cartridge and the blade changer, thus adding an element of intelligence to the blade changer.

The supply cartridge may also serve to function as a waste cartridge for accepting spent blades. Again with reference to Fig. 3C, cross-section C-C shows an entrance 145 for used blades. The supply cartridge is oriented on upper stage body 5 in reverse so that entrance 145 receives spent blades as they are pushed out of the cutting position by a new blade. As the user continues to load new blades, used blades accumulate in the reversed supply cartridge now functioning as a waste cartridge. Spring 107 will be pushed towards the top 120 of the cartridge as waste blades accumulate. The microcontroller will signal the user that the waste cartridge is filled when the microcontroller has recorded the maximum number of allowable blades. Alternatively, a dedicated waste cartridge is also possible, and is depicted in Figs. 5A-C.

Again with reference to Fig. 3, supply cartridge 15 has a dispensing tab 90 integral with the cartridge and adapted for engaging each new blade 95. Downward protrusion 92 engages a slot or opening in each new blade. The downward protrusion may be a metal tab, a plastic hook or similar equivalent article. The main design limitation is that it reliably contact only one blade at a time. Downward protrusion 92 may be located anywhere on dispensing tab 90 so long as it functions to urge a single blade out of the cartridge for each cycle of the loading segment 30. In the preferred embodiment shown in Fig. 3, the protrusion is forward mounted on the blade side of

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dispensing tab 90. A second embodiment of the dispensing tab is shown in Figs. 7-8. The primary feature is that dispensing tab shown (290) is designed with a slot or cutout for engaging shuttle tab 231. It does not have the teeth necessary for engaging the loading segment 30, which is not present in this embodiment.

5           The safety interlock feature will now be described with more particularity. The safety interlock feature includes touch memory device 150 mounted on the cartridge (Figs. 3A-3B, 7-8), an on-board PIC microcontroller contained within the blade changer for running the operations of the device while being in communication with the touch memory device, a contact reader (not shown) for the data button, and electronically-  
10       controlled locking mechanisms for the cartridges. The touch memory device is described in U.S. Serial Patent Number 08/995,052 6,045,759, filed December 19, 1997 and issued April 4, 2000, incorporated herein by reference in its entirety. In a preferred embodiment, the memory device is an EPROM such as the Dallas Semiconductor DS1985 F5 16 Kbit add-only touch memory device. Its primary function is to initialize  
15       the safety interlock system for each new blade cartridge that is presented to the blade changer. The touch memory device contains information such as the number of blades, date of expiration, lot no., etc. In operation, the touch memory device is initially read-in the number of blades in the cartridge when loaded with blades at the factory. When the cartridge is loaded into the supply position on the blade changer, contacts on the  
20       cartridge connected to the touch memory device, or the touch memory device itself, make electrical contact with a touch memory reader (not shown) which is built into the upper stage so that as the cartridge seats itself it contacts the touch memory reader. The on-board microcontroller then tracks the position and number of blades left in the cartridge until the cartridge is empty. The on-board microcontroller will then notify the  
25       user through an interface such as LEDs or LCD readout. The on-board microcontroller executes the blade loading functions and maintains a look-up table that correlates blade position with steps executed, and so it tracks where the blades are at all times, and most importantly, whether blades are outside of the cartridges (and a potential safety hazard). If they are, then the interlock function will not allow the cartridges to be removed until  
30       the blades are within their respective cartridges. Safety interlocks 155 (Figs. 2, 8) are mechanical- or solenoid-operated latches or arms that retain the cartridge in position,

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until activated by the microcontroller to release the cartridge. A hole or other ledge for the latch to attach to is located on the cartridge on the side facing the upper stage.

The cycle portion of the operation of the blade changer will now be described, with particular reference to Figs. 2 and 4. Starting with loading a new blade cartridge, a new supply cartridge 15 is loaded into the upper stage body 5, and locks into position. To eject a new blade 95 from supply cartridge 15, the user presses the blade advance push-button 76 on key pad 15 75. Switch 15 76 is in electrical communication with the microcontroller which then activates motor 10 50. Motor 50 ~~is actuated~~ actuates driving gear 55 and pulley gear 60 which cause rotation of drive shaft 65. This action then causes the loading and clamping cams 40 and 45, respectively, to move in fixed relation with each other. These cams are oriented on the drive shaft so that the clamping cam 45 is not engaged with the clamping plate 20 for the first half-turn of drive shaft 65 while loading cam 40 is moving loading segment 30 from right to left and consequently dispensing tab 90 moves the first part of the new blade into the cutting area.

During the second half-turn of drive shaft 65 clamping cam 45 engages with clamping plate 20 causing the blade to be clamped in the cutting position while the loading cam 40 moves the loading segment 30 and the dispensing tab 90 from left to right. In the middle of this move the microcontroller stops motor 50 and the blade 100 95 stays clamped ready for cutting.

When the new blade 95 is pushed from the supply cartridge 15 to the cutting area it pushes the used blade ~~[[100]]~~ from the cutting area to waste cartridge 10. This design allows partial movement of the new blade 95 in one direction (1/3 of a blade width with each back-and-forth cycle of the loading segment), in order to maximize use of the blade for small tissue blocks. It takes three full cycles of the dispensing tab to fully eject and position new blade 95. More particularly and with reference to Figs. 4A-4D, Fig. 4A shows the supply cartridge 15 at rest with the new blade 95 concealed from view within the cartridge (start position). As loading segment 30 (not shown in this view) is activated, it engages the teeth on dispensing tab 90 which then pushes new blade 95 one third of its length out of the housing (Fig. 4B). As loading cam 40 rotates, the direction of dispensing tab 90 is then reversed by loading segment 30, and the tab moves back to its starting position. The second cycle repeats the left-right motion of the dispensing tab,

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pushing the blade yet another one-third of its length (Figs. 4C and 4D) per cycle. Fig. 4D shows a fully ejected new blade 95. Clearly an alternative embodiment which pushes the blade out a different fraction of its length, such as  $\frac{1}{4}$ , or  $\frac{1}{5}$ , is also within the spirit and scope of this invention.

5 Referring again to Fig. 2, ~~the used blade 100~~ 95 is pushed out of its cutting position by the action of the new blade 95 being urged out of the supply cartridge, as previously described. The two blades occupy the same plane, and so as a new blade is ejected, it engages the old blade at their common edges. ~~The Used~~ used blade ~~[[100]]~~ is pushed into waste cartridge 10, which may be an empty supply cartridge adapted to fit  
10 into upper stage body 5 (Fig. 5), or it may be an empty supply cartridge being reversible and having an entrance 145, as previously described. In an alternate embodiment, a dedicated waste cartridge may be used. In Figs. 5A-C, such a cartridge is shown. It shares many of the same components as the supply cartridge.

A second embodiment of the blade changer comprises lower and upper stage  
15 bodies 201, 205, respectively. With reference to Figs. 7-8, the microtome blade cartridges are removably located within the upper stage body 205. The lower stage body is adaptable to a wide variety of rotary microtomes, and serves as the common interface mounting for the upper stage. The disposable blade cartridges 210, 215 are adapted to lock into the upper stage body 205 so as to provide an element of safety. The cartridges  
20 are described more fully in the first embodiment and in Figs. 3-5. In this second ~~embodiment~~ embodiment they differ only in that the dispensing tab 90 (Figs. 1-2) is replaced by dispensing tab 290 (Fig. 7-8). The cartridges are releasable only when the individual blades are fully secured within the body of the cartridge. This "interlock" function can be attained in many ways, however a preferred embodiment includes an on-  
25 board microcontroller which monitors the state of operation of the blade changer. When the controller's logic functions determine that no blade edges are exposed, then the clamping plate and/or the cartridges may be released. The interlock function is more fully described below. The clamping means includes clamping plate 20, support plate 25, and clamp pivot rod 112 which together function to clamp the blade in the cutting  
30 position during use of the blade in the microtome. Reverser shuttle 230 has a shuttle tab portion 231 mounted to engage the slot ~~231~~ 292 in dispensing tab 290. Dispensing tab

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290 is integral with the supply cartridge 215. Reverser shuttle 230 has a threaded portion (not shown) which engages reverser screw 240. The function of reverser shuttle 230 is to move dispensing tab 290 of the blade supply cartridge 215 thereby urging new blades 95 to the central cutting area. As shown by Figs 3-4, this is performed through  
5 downwardly protruding member 92 which engages a slot or hole 96 formed in the body of blade 95 which enables dispensing tab 290 to engage the topmost blade in its stored position at the top of the stack of blades contained within supply cartridge 215. Reverser screw 240 is supported on either end by bearings 241 which are supported and retained by upper stage body 205. Reverser shuttle 230 engages reverser screw 240 through  
10 through helical cutout 232 and mating helical threads (not shown) located on the shuttle 230. In a ~~preferred~~ preferred embodiment, ~~reverser~~ reverser shuttle 230 acts like a threaded nut and moves laterally at the urging of reverser screw 230. The helical cutout of reverser screw 230 is unique in that the reverser shuttle will move back and forth without a ~~concomitant~~ concomitant change in direction of any other component in the  
15 drive train. Similar reverser screws are common and well-known in the ink-jet printer art.

Power means comprises bidirectional DC motor 250 which rotates drive shaft 265 and drive gear 255, which in turn engages reverser screw gear 260. Reverser screw gear 260 in turn is attached to reverser screw 240, and when rotational motion is applied  
20 through drive shaft 265 the result is rotational motion in reverser screw 240, and thus the threads of reverser shuttle 230 will be urged to move laterally along the helical cutout. Drive shaft 265 also simultaneously moves clamping plate 20 forward and backward in order to either clamp or release a blade in the cutting area. The motor is bidirectional so that clamp pivot rod 112 may be released only when the motor is reversed. This function  
25 would require a clutch mechanism that in forward (normal) operation engages a groove in the rod, which stops the rod from being removed from the blade changer. Since removal of the rod is a precursor to removal of the clamping plate for cleaning access, this is another safety interlock feature of the device.

The reverser screw 240 and clamping cam 45 are coordinated so that reverser  
30 shuttle 230 can only push a new blade 95 into position when clamping plate 20 is open



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(pressure relieved from the blade). It is well within the skill in the art to design and position the two cams to effectuate this coordinated function.

The functional advantages of the invention described above are numerous. First, the blades are moved into the cutting area completely without manual contact. Second, 5 blades are moved into the waste cartridge for disposal completely without manual contact. Third, moving the blades automatically, by push-button switch or by manual lever, is a fast, efficient way to load and unload.

Although certain presently preferred embodiments of the invention have been described herein, it will be apparent to those skilled in the art to which the invention 10 pertains that variations and modifications of the described embodiment may be made without departing from the spirit and scope of the invention. Accordingly, it is intended that the invention be limited only to the extent required by the appended claims and the applicable rules of law.